



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Pharmacotherapy for Adults with Alcohol-Use Disorders in Outpatient Settings: Systematic Review Update

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Pharmacotherapy for Adults with Alcohol-Use Disorders in Outpatient Settings: Systematic Review Update*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

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FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Pharmacotherapy for Adults with Alcohol-Use Disorders in Outpatient Settings: Systematic Review Update*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on

Pharmacotherapy for Adults with Alcohol-Use Disorders in Outpatient Settings:

Systematic Review Update, including those that describe adverse events. The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/alcohol-misuse-drug-therapy/protocol>

This is to notify the public that the EPC Program would find the following information on Pharmacotherapy for Adults with Alcohol-Use Disorders in Outpatient Settings: Systematic Review Update helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
 - *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The systematic review will answer the questions below. This information is provided as background and AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1a: Which medications are efficacious for improving consumption outcomes for adults with alcohol-use disorders in outpatient settings?

KQ 1b: How do medications for adults with alcohol-use disorders compare for improving consumption outcomes in outpatient settings?

KQ 2a: Which medications are efficacious for improving health outcomes (including functioning and quality-of-life outcomes) for adults with alcohol-use disorders in outpatient settings?

KQ 2b: How do medications for adults with alcohol-use disorders compare for improving health outcomes (including functioning and quality-of-life outcomes) in outpatient settings?

KQ 3a: What adverse effects are associated with medications for adults with alcohol-use disorders in outpatient settings?

KQ 3b: How do medications for adults with alcohol-use disorders compare for adverse effects in outpatient settings?

KQ 4: Are medications for treating adults with alcohol-use disorders effective in primary care settings?

KQ 5: Are any of the medications more or less effective than other medications for older adults, younger adults, smokers, or those with co-occurring disorders?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

- **Population(s)**

- Adults (age 18 years or older) with alcohol-use disorders

- **Interventions**

- Pharmacotherapy for relapse prevention. This includes:
 - Medications approved by FDA for treating alcohol dependence:
 - acamprosate
 - disulfiram
 - naltrexone (oral or injectable)
 - Certain medications in use off label that are available in the United States:
 - baclofen

- gabapentin
 - ondansetron
 - topiramate
 - prazosin
 - varenicline
- Studies evaluating pharmacotherapy that used co-interventions with other treatments for AUDs (e.g., behavioral counseling, cognitive behavioral therapy, motivational enhancement therapy, psychosocial treatments, or self-help such as 12-step programs [e.g., Alcoholics Anonymous]) will be eligible for inclusion, as long as they meet other inclusion/exclusion criteria.
- This review will not include pharmacotherapy for alcohol withdrawal.
- **Comparators**
 - Studies must compare one of the medications listed above with placebo or another eligible medication.
- **Outcomes**
 - Consumption outcomes
 - abstinence/any drinking
 - rates of continuous abstinence
 - percentage of days abstinent
 - time to first drink/lapse
 - time to heavy drinking/relapse
 - reduction in alcohol consumption
 - number of heavy drinking days
 - percentage of subjects with no heavy drinking days
 - number of drinking days
 - drinks per drinking day

- drinks per week
- Health outcomes
 - accidents
 - injuries
 - quality of life
 - function
 - mortality
- Adverse effects of intervention(s)
 - withdrawals due to adverse events
 - nausea/vomiting
 - diarrhea
 - anorexia
 - palpitations
 - headache
 - dizziness
 - cognitive dysfunction
 - taste abnormalities
 - paresthesias (numbness, tingling)
 - metabolic acidosis
 - glaucoma
 - vision changes
 - suicidal ideation
 - insomnia
 - anxiety
 - rash
 - tiredness

- weakness
 - constipation
- **Timing**
 - Studies with at least 12 weeks of planned pharmacologic treatment and followup from the time of medication initiation
- **Setting**
 - Outpatient healthcare settings; KQ 4 applies to primary care settings only (i.e., internal medicine, family medicine, obstetrics/gynecology, or college and university health clinics)

Dated: May 12, 2022.

Marquita Cullom,

Associate Director.

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